National Cancer Institute Institutional Review Board

AGENDA March 23, 2015

1:00 - 5:00 pm 10 CRC/3-1608

- 1. Review of Draft Minutes, March 9, 2015
- 2. Announcements
- 3. Old Business
 - Progress Report for Dr. Kreitman's Protocols
- 4. New Business
 - NCI Consent Form Template
- 5. Problem Report Forms
- 6. Other Expedited Actions
- 7. Continuing Reviews
- **8. Amendment** 02C0077-N, "Characterization of High Risk Breast Duct Epithelium by Cytology, Breast Duct Endoscopy, and cDNA Gene Expression Profile" David Danforth, PI
- **9. Amendment** 09C0025-N, "Phase II Trial of LMB-2, Fludarabine and Cyclophosphamide for Adult T-Cell Leukemia" Robert Kreitman, PI
- **10. Amendment**10C0114-K, "A Phase II Study of Bevacizumab and Erlotinib in Subjects with Advanced Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC) or Sporadic Papillary Renal Cell Cancer" Ramaprasad Srinivasan, PI
- **11. Initial Review** P141760, "A Phase 1 Study of Subcutaneous Recombinant Human hetIL-15 (IL15 / sIL-15Ra) in Adults with Metastatic Cancers" Kevin Conlon, PI
- **12. Initial Review** P141998, "Clinical Sequencing of Cancer and Tissue Repository" Javed Khan, PI
- P141739, "A Phase II Study of the Anti-CD22 Recombinant Immunotoxin Moxetumomab Pasudotox (CAT-8015, HA22) in Children with B-lineage Acute Lymphoblastic Leukemia and Minimal Residual Disease Prior to Allogeneic Hematopoietic Stem Cell Transplantation" Nirali Shah, PI